

***EXAMINER'S AMENDMENT/COMMENT***

Applicant's filing of the RCE and amendment to only the claims indicated as allowable in the Final Rejection of 1/23/09, is acknowledged.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The Examiner left a telephone message regarding the formality examiner's amendment with Matthew Hierholzer, Applicant's Representative, on 10/12/09. [Re: Internal U.S. Patent Office Memorandum that the term "a/an" may not precede the term "peptide" but rather the term "the" must, to avoid any misinterpretation that a fragment peptide (e.g. any dipeptide) of any claimed peptide may be the subject matter of the invention. Such is the case here, where at least full length SEQ ID NO: 7 must be present (e.g. no fragment peptide thereof), to which the subject matter of the invention and prosecution/examination thereof have been directed throughout].

**IN THE CLAIMS**

In claim 117, line 3, the term "a" is deleted and the term --the-- inserted.

In claim 124, line 2, the term "a" is deleted and the term --the-- inserted.

***Election/Restrictions-Withdrawn***

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been cancelled by Applicant, **the restriction requirement as set forth in the Office action mailed on 7/12/06 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that *if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971).* See also MPEP § 804.01.

***REASONS FOR ALLOWANCE***

The following is an examiner's statement of reasons for allowance:

Applicant's amendment of the claims to only claims 117-130 in a method of treating inflammation in a subject in need thereof, using the artificial/synthetic peptide of SEQ ID NO: 7, was not found to be reasonably taught or suggested by the prior art of record.

As stated on the Form 37 of the Final Rejection of 1/23/09, claims 117-130 are allowed.

As discussed substantively therein, under the heading "Allowable Subject Matter" "...the methods of treating inflammation [independent claim 117] and sepsis [independent claim 124], using a peptide of SEQ ID NO: 7, were not found to be reasonably taught or suggested by the prior art of record. The reasons for allowance are found in the Affidavit/Declaration

submitted 8/21/09:

A. Pages 4-5, under the Title: Efficacy against Inflammation; which provide the test data of efficacy of SEQ ID NO: 7 in treating inflammation in *in vivo* infection models (Fig's 6-8); and

B. Page 8, under the Title: Efficacy in Sepsis Models; "As an extension of the anti-inflammatory activity elicited by SEQ ID NO: 7 [ ], a reduction in sepsis is expected. This is demonstrated by the upregulation of CCL5 (RANTES; Fig. 10), a positive prognosticator of sepsis outcome in a clinical setting, and by the activity of the related peptide, SEQ ID NO: 6 in a sepsis model (Fig. 11)."

The isolated peptide of SEQ ID NO: 7 was allowed in claim 1 of parent SN 10/308905 (now US 7507787). However, neither the presently claimed method of use nor functional language thereto within the issued product are present in the parent '905 (restriction requirement between independent and distinct products and methods therein made Final; finality not withdrawn at allowance). The present application family also includes a child continuation-in-part application SN11/241,882, which remains under examination to an assay method directed to different steps, compounds (gene, polynucleotides, peptides such as any of SEQ ID NO: 3-54), and end results. Thus, the parent and child of the present application being directed to independent and distinct products or methods, there are no double patenting warranting terminal disclaimer, found at the time of this writing.

It is noted that claims 118 and 125, drawn to the peptide of SEQ ID NO: 7 containing at least one amino acid that is a "D-enantiomer" finds inherent support for the term enantiomer in paragraph 74 of the published application (US 20040180038) discussing the same as D and L

“configuration” of amino acids. The terms configuration and enantiomer find overlapping use in the peptide arts for various systems of labeling an amino acids direction/form (e.g. +/-; R/S, D/L, d/l; see merely by example as well known in the art, and thus noted but not needed to be made of record: [http://en.wikipedia.org/wiki/Chirality\\_\(chemistry\)](http://en.wikipedia.org/wiki/Chirality_(chemistry))).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

### *Conclusion*

Claims 117-130 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 10/12/2009

/Maury Audet/  
Examiner, Art Unit 1654  
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